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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 09/945,225 | 08/31/2001 | Ting Tina Ye | 1001.1471102 | 3493 |
| 28075 | 7590 | 01/28/2004 | EXAMINER | |
| CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420 | | | DESANTO, MATTHEW F | |
| | | ART UNIT | PAPER NUMBER | |
| | | 3763 | DATE MAILED: 01/28/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/945,225 | YE ET AL. |
| | Examiner Matthew F DeSanto | Art Unit 3763 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 November 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

| | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Samson et al. (USPN 6090099). Samson et al. discloses a catheter comprising an elongated shaft, having a proximal end, a distal end and a distal tip, wherein the shaft includes an inner liner, a second layer disposed on the inner layer, a third layer disposed on the second layer and a fourth layer disposed on the third layer and wherein the first segment extends to a distal terminus and the second segment extending from the distal terminus to a radiopaque marker disposed proximal of the distal end of the shaft. (Figure 2).

Wherein the liner comprises polytetrafluoroethylene. (Column 6, lines 16-22).

Wherein the distal tip has a shapable length and the distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapable length. (Figure 1 and 2).

Wherein the distal tip can be heat set by steam. (Column 6, lines 30-31).

Wherein the third layer comprises a coil, and where the coil comprises steel, nickel or a non-ferrous metal. (Column 6 line 51 – Column 8, line 11).

Wherein the distal end of the shaft has an outside diameter that is less than the diameter of the proximal end of the shaft, and where the durometer is less as the distal end than at the proximal end. (Column 8, lines 49-67).

Wherein the second layer further comprises a second segment, and the second segment is disposed at the inner liner between the distal terminus and the distal end of the shaft. (Figure 2).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2, 3, 4, 5, 7, 8, 9, 10, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sampson et al. Sampson et al. discloses the claimed invention except wherein the distal terminus is about 4 millimeters from the distal end. It would have been an obvious matter of design choice to one skilled in the art to modify the apparatus as taught by Sampson et al. to have a distal terminus 4 millimeters from the distal end, since applicant has not disclosed that 4 millimeters provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any length from the distal terminus, such as the length as taught by Sampson et al.

which is less than 2 centimeters as taught by Sampson et al. for the reasoning of allowing a more flexible distal end.

5. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sampson et al. as applied to claims 1, 2, 3, 4, 5, 7, 8, 9, 10, 12 and 13 above, and further in view of Nita et al. (5951539).

Sampson et al. disclosed the claimed invention as mention above, but fails to teach the use of polyether block amide for the second and fourth layers, as well as having a multiple coil section in the proximal area and wherein the fourth layer has a greater durometer in the proximal end then in the distal end.

Nita et al. discloses an intravascular catheter with an inner layer lubricious liner, a first, helically wound coil extending over at least the more distal portions of the inner liner but preferably for most of the length of the catheter, a second, helically wound coil exterior to the first coil, located at least on the more proximal portion of the assembly but preferably for most of the length of the catheter, preferably wound in a direction opposite to the first coil, optionally, one or more helically wound coils placed on the proximal and mid-section of the assembly, and one or more polymeric layers variously exterior to the second coil and interior to the first coil. Further polymeric layers may also be placed between the outer polymeric covering and various and the helically wound coils. The outer polymeric covering may be composed of a series of different polymeric compositions to provide suitably differing flexibilities along the length of the assembly. The helically wound coils may be bound to the assembly via the use of radio-opaque bands or coils and may be continuously wound from a single member. The distal-most

portion of the catheter assembly is very flexible but highly kink resistant. Optionally, the invention includes a catheter in which only the more distal catheter section incorporates multiple coil stiffener members. (Figures 2E, 2F, 4, 7, 8, 9, and 10).

At the time of the invention it would have been obvious to one of ordinary skill in the art to combine Sampson et al. with Nita et al. because Nita et al. taught having outer polymeric tubing sections with different durometers (Column 12, lines 46-62), which allows for an increase in flexibility and maneuverability. Nita et al. also taught having a single coil in the distal end and then multiple coils in the proximal end, which allows for a greater "pushability" (Column 9, lines 9-27). Nita et al. also disclosed using polyether block amide in the polymeric layers because of the qualities the composition possess in the area of torsion modulus, flexibility and column strength.

Therefore, it would have been obvious to combine Sampson et al. with Nita et al. to obtain the invention as specified in claims 1-21.

Response to Arguments

6. Applicant's arguments filed 11-24-03 in paper number 12 have been fully considered but they are not persuasive because the examiner holds the limitation "shapeable by thermoforming techniques" to be a product by process limitation. The examiner is interpreting thermoforming techniques to be a method of manufacturing the claimed catheter and since this is an apparatus claim that limitation is then interpreted as a product as process wherein the product is the claimed catheter and the process is the thermoforming techniques. Therefore, the examiner is keeping the rejection

because he is interpreting the phase "shapeable by thermoforming techniques" under the rules of MPEP and the cited case law; thus the catheter has to have the same structure (the final product) since this is an apparatus claim and prior art teaches the claimed invention. [See *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957); *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978), and *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).]

7. Since this is an apparatus claim the examiner suggests finding structural that overcomes the prior art.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

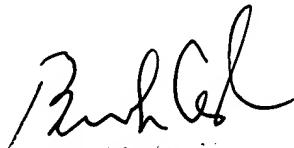
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 1-703-872-9302 for regular communications and 1-703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1-703-308-0858.


Matthew DeSanto
Art Unit 3763
January 22, 2004


BRIAN L. CASLER
SUPERVISOR
TECHNOLOGY
ART UNIT 3763